

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

04 MBD 10128

ALLEN A. MITCHELL, M.D.,
SAMUEL M. LESKO, M.D.,
TRUSTEES OF BOSTON UNIVERSITY,

Plaintiffs,

vs.

KERRY LANGSTAFF and
BRADSHAW LANGSTAFF,
Individually, and on Behalf of
KAITLYN SIERRA LANGSTAFF,
a minor child,

Defendants.

Civil Action No. 04 -MBD-

Related Civil Action:

United States District Court for the Northern
District of California, San Jose Division,
Civil Action No. 03-CV-01116-HRI.

KERRY LANGSTAFF and
BRADSHAW LANGSTAFF,
Individually, and on Behalf of
KAITLYN SIERRA LANGSTAFF,
a minor child,

vs.
MCNEIL CONSUMER &
SPECIALTY PHARMACEUTICALS,
a Division of MCNEIL-PPC, INC.; and
JOHNSON & JOHNSON.

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION
TO QUASH DEPOSITION SUBPOENAS AND SUBPOENAS DUCES TECUM
PURSUANT TO FED. R. CIV. P. 45(c)(3)(A) and (B)

Plaintiffs, Allen A. Mitchell, Samuel M. Lesko, and Trustees of Boston University (collectively "Plaintiffs") move to quash the deposition subpoenas and subpoenas duces tecum served upon Drs. Samuel Lesko and Allen Mitchell. Dr. Mitchell is the Director of the Slone Epidemiology Center at Boston University ("Slone") and Dr. Lesko is an adjunct faculty member at Boston University, who was formerly employed by the Slone Epidemiology Center. Dr. Lesko was served with a subpoena on April 9, 2004, requiring him to appear for a deposition on May 27, 2004, on behalf of the plaintiffs in Langstaff, et al. vs. McNeil Consumer & Specialty Pharmaceuticals, et al. (Case No. 03-CV-01116-HRI., N.D. Cal.). Exhibit 1. Dr. Mitchell was served with an identical subpoena on April 26, 2004, requiring him to appear

for a deposition on behalf of Langstaff Plaintiffs¹ on May 26, 2004. Exhibit 2. Neither doctor has been retained as an expert by either party to the underlying action, and both subpoenas require the doctors to provide substantial numbers of documents related to their previous research. Langstaff Plaintiffs have not indicated the subjects on which they intend to depose Drs. Lesko and McNeil.

BACKGROUND

Dr. Mitchell is the Director of the Slone Epidemiology Center at Boston University and Dr. Lesko, until 2000, was employed by Slone in the role of senior investigator. Between February of 1991 and June of 1993, Drs. Mitchell and Lesko conducted a randomized double-blind office-based clinical trial among children with fevers to assess the risks of rare but serious adverse events following the use of pediatric ibuprofen. Pediatric ibuprofen has been available by prescription since 1989, but in 1991 had not yet been approved for over-the-counter use. This study, which was supported by McNeil Consumer Products Company ("McNeil"),² one of the manufacturers of pediatric ibuprofen, was designed to gather additional safety data on pediatric ibuprofen, with the goal of seeking approval through the U.S. Food and Drug Administration ("FDA") for over-the-counter use. The control for the study was the drug acetaminophen, which was the drug of choice for the treatment of fever in children, and which had been available over-the-counter for some time.

A total of 1,735 physicians enrolled their patients in the study. The study subjects were children between six months and twelve years of age who were seen by the physicians for an

¹ The term "Langstaff Plaintiffs" will be used to refer to the plaintiffs in the underlying case of Langstaff, et al. vs. McNeil, et al. Civil Action No. 03-CV-01116-HRI, United States District Court for the Northern District of California.

² The present name of the company is "McNeil Consumer & Specialty Pharmaceuticals."

acute febrile illness and who met other specified criteria for enrollment. A total of 84,192 children participated in the study, and these children were randomly assigned to receive acetaminophen or ibuprofen. The hypothesis being tested was whether ibuprofen increases (relative to acetaminophen) the risk of hospitalization for gastrointestinal bleeding, renal failure, anaphylaxis, or Reye's Syndrome. Information was gathered by means of a questionnaire that was sent to the parent or guardian of each participant and that asked, among other things, about the occurrence of any serious medical events in the four weeks following enrollment that required a visit to an emergency department, physician's office, or hospitalization.

Drs. Mitchell and Lesko concluded that the risk of hospitalization for gastrointestinal bleeding, renal failure, anaphylaxis, or Reye's Syndrome was not increased following short-term use of ibuprofen in children. They did not opine on the risks of less severe outcomes or the risks of prolonged ibuprofen use. The study has become known as the "Boston University Fever Study."

All study data gathered by Drs. Mitchell and Lesko was provided to McNeil, which in turn submitted both the results of the study and all of the underlying data to the FDA.

Drs. Mitchell and Lesko's findings were also published in several articles. See, for example, Lesko SM, Mitchell AA. *An assessment of the safety of pediatric ibuprofen: a practitioner-based randomized clinical trial*. JAMA. 1995; 273: 929-933. The FDA ultimately approved McNeil's pediatric ibuprofen (marketed as Children's Motrin) for over-the-counter use.

UNDERLYING LAWSUIT

On March 14, 2003, Kerry Langstaff, et al., brought a products liability suit against McNeil Consumer & Specialty Pharmaceuticals alleging that Kaitlyn Langstaff, a minor child,

developed Stevens Johnson Syndrome ("SJS") and toxic epidermal necrolysis ("TEN") because of a reaction to Children's Motrin. Both SJS and TEN are serious dermatological disorders.

On April 9, 2004, and April 26, 2004, Langstaff Plaintiffs served deposition subpoenas and subpoenas duces tecum upon Drs. Samuel Lesko and Allen Mitchell. Exhibits 1 and 2. Langstaff Plaintiffs have not enumerated the topics about which they seek to depose Drs. Lesko or Mitchell. The subpoenas request Drs. Mitchell and Lesko to produce documents that are identical to documents set forth in earlier subpoenas duces tecum that were served by Langstaff Plaintiffs upon the Custodian of Records for Slone and the Custodian of Records for Allen Mitchell in November of 2003. Exhibits 4, 5. Slone and Dr. Mitchell served upon Langstaff Plaintiffs written objections to the inspection or copying of the designated materials pursuant to Fed. R. Civ. P. 45(c)(2)(B). Exhibit 6. Langstaff Plaintiffs did not move to compel, as is required under Rule 45(c)(2)(B), but rather included the documents in the deposition subpoenas served upon Drs. Mitchell and Lesko.

JURISDICTION

Although Dr. Mitchell's subpoena was issued from the District Court for the Northern District of California, he is commanded to appear for a deposition and produce documents in Boston, Massachusetts. See Exhibit 2. The Federal Rules of Civil Procedure provide that "a subpoena for a deposition shall issue from the court for the district designated by the notice of deposition as the district in which the deposition is to be taken." Fed. R. Civ. P. 45(a)(2). Likewise, a subpoena for production of documents must issue from the court for the district in which production is to be made. Id. This Court should take jurisdiction over matters relating to Dr. Mitchell's subpoena because, pursuant to Fed. R. Civ. P. 45(a)(2), his subpoena should have issued from the United States District Court for Massachusetts. Plaintiffs should not be forced to

travel to California to contest a subpoena that was not lawfully issued, and Plaintiffs should be allowed to litigate the validity of the subpoena in Massachusetts where Dr. Mitchell is located. See Echostar Communications Corp. v. The News Corporation, Ltd., 180 F.R.D. 391, 397 (D. Colo. 1998)(nonparties should not be forced to litigate validity of subpoena in jurisdiction from which it wrongly issued); Kupritz v. Savannah College of Art and Design, 155 F.R.D. 84, 88 (E.D. Pa. 1994)(court from which subpoena should have issued finds subpoena issued from wrong court to be invalid).

Although Dr. Lesko presently resides in Scranton, Pennsylvania, Langstaff Plaintiffs chose to issue his subpoena through the United States District Court for Massachusetts, presumably because the documents requested in the subpoena related to Dr. Lesko's work on the Boston University Fever Study while he was employed at Boston University.³ See Exhibit 1. This Court therefore has jurisdiction over matters relating to Dr. Lesko's subpoena pursuant to Fed. R. Civ. P. 45(c)(3)(A), which provides that motions to quash or modify a subpoena should be made to "the court by which a subpoena was issued." Moreover, as Dr. Lesko's subpoena is identical to the subpoena issued for Dr. Mitchell, (with the same nineteen document production requests), it makes sense, in the interest of judicial economy, for this Court to rule on Dr. Lesko's motion to quash as well.

SUMMARY OF ARGUMENT

Drs. Mitchell and Lesko should not be subject to deposition because they fall within the protections of Rule 45(c)(3)(B)(ii) and Langstaff Plaintiffs have not made a showing of a

³ Because Dr. Lesko is commanded to appear for deposition and produce documents in Scranton, Pennsylvania, Langstaff Plaintiffs' subpoena should have issued from the District Court for the Middle District of Pennsylvania pursuant Fed. R. Civ. P. 45(a)(2). However, because the subpoenas relating to Dr. Mitchell and Dr. Lesko are identical, Plaintiffs request this Court to hear both motions and to rule on the substantive grounds set forth by Plaintiffs for quashing both subpoenas.

substantial need for their testimony that cannot otherwise be met without undue hardship. The factors to be considered, as set forth in the test described in Kaufman v. Edelstein, 539 F.2d 811, 822 (2d Cir. 1976), a case cited with approval by the Federal Rules Advisory Committee, militate against allowing these depositions to go forth.

Langstaff Plaintiffs are on a fishing expedition. Kaitlyn Langstaff suffered an event that was not identified in any child in the Boston University Fever Study. Langstaff Plaintiffs' demands for deposition and documents would only be relevant, therefore, if Langstaff Plaintiffs were seeking to show that Drs. Mitchell and Lesko, either on their own or with the collusion of McNeil, designed, conducted, or analyzed the study in such a way as to specifically eliminate from the study any occurrence of SJS/TEN. Langstaff Plaintiffs have not provided even a scintilla of evidence in support of such an allegation. Their demands, therefore, are designed either as a fishing expedition or to intimidate Drs. Mitchell and Lesko, or both.

Further, this Court should exercise its discretion to quash the burdensome subpoenas duces tecum served upon Drs. Mitchell and Lesko because many of the requests are duplicative of discovery materials that have already been provided to Langstaff Plaintiffs by McNeil. Requiring Drs. Lesko and Mitchell or Slone to expend substantial time and resources to locate and make available for inspection the identical documents is burdensome and unnecessary.

The subpoenas seek production of confidential contracts, communications, and business dealings between Drs. Mitchell and Lesko, Slone, and McNeil, including copies of private contracts between Slone and McNeil. Langstaff Plaintiffs can make no showing that a fishing expedition into the general business relationship between Slone and McNeil has any relevance to their lawsuit against McNeil, and they have no reasonable basis for seeking such documents

other than to harass Drs. Mitchell and Lesko or to obtain confidential research, development or commercial information in violation of Rule 45(c)(3)(B).

The subpoenas seek disclosure of the names and addresses of the approximately 1,700 physicians who participated in the Boston University Fever Study. Providing such information will chill physicians' cooperation in ongoing research studies if, as a consequence of participation, the physicians are contacted by Langstaff Plaintiffs seeking to verify information obtained from researchers about them. Such physicians might also knowingly or unknowingly provide information that would allow Langstaff Plaintiffs to identify particular patients.

Finally, the subpoenas contain requests that bear virtually no relevance to the subject matter of the litigation, and the resources necessary to obtain the information requested is highly disproportionate to the relevance of the information.

ARGUMENT

1. RULE 45 OF THE FEDERAL RULES OF CIVIL PROCEDURE AND JUDICIAL OPINIONS GIVE THIS COURT THE DISCRETION TO QUASH THE DEPOSITION SUBPOENAS.

Rule 45(c) of the Federal Rules of Civil Procedure details the protections afforded to non-party witnesses who are subject either to a subpoena for the purpose of taking their deposition or a subpoena duces tecum requiring the production of documentary evidence. Subparagraph (c)(3)(B)(ii) of Rule 45 states that, under certain enumerated circumstances, a court "may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena." Alternatively, if the party issuing the subpoena shows a substantial need for the testimony or material that cannot be otherwise met with undue hardship, the court may order appearance or production upon specified conditions, provided that the issuing party "assures

that the person to whom the subpoena is addressed will be reasonably compensated.”

Rule 45(c)(3)(B)(iii).

One of the circumstances enumerated in Rule 45(c)(3)(B) as a basis for a motion to quash is a subpoena that “requires disclosure of an unretained expert’s opinion or information not describing specific events or occurrences in dispute and resulting from the expert’s study made not at the request of any party.” Here, although Drs. Mitchell and Lesko initially conducted the Boston University Fever Study at the request of McNeil, this was to done to assist McNeil in possibly obtaining initial FDA approval of the drug for over-the-counter use, and had no relation to this litigation. As such, they should be deemed to fall under the protections of this rule.

Schering Corp. v. Amgen, Inc., 1998 WL 552944 (D. Del.).

A. Drs. Lesko and Mitchell Should Not Be Treated as Fact Witnesses.

While Langstaff Plaintiffs may contend that Drs. Mitchell and Lesko should not be treated as unretained experts because they are only seeking “fact testimony,” such a contention would be “disingenuous.” See Schering 1998 WL 552944 at * 2 n.3. Langstaff Plaintiffs’ lawsuit concerns a specific injury caused to Kaitlyn Langstaff, allegedly due to her ingestion of a drug manufactured by McNeil. Drs. Mitchell and Lesko have no information regarding Kaitlyn Langstaff’s injuries, nor can they testify whether any individual user of Children’s Motrin suffered harm as a direct or indirect use of the drug. Their study was not designed to investigate whether, in a given patient, exposure to ibuprofen (or acetaminophen) caused a particular adverse event. Their testimony in this case would necessarily be focused on the methodology and conclusions of the Boston University Fever Study, all of which are clearly set forth in their published articles.

Langstaff Plaintiffs are interested in deposing Drs. Mitchell and Lesko precisely because they assume (though McNeil has not retained them as experts) that McNeil will rely upon the Boston University Fever Study in defending against Langstaff Plaintiffs' claims. It is for this reason that Langstaff Plaintiffs have requested copies of the doctors' current CVs as well as a list showing all cases in which they have testified as an expert dealing with the drug ibuprofen as well as any expert reports. See Exhibit 1, Request Nos. 1, 2, and 18.

Langstaff Plaintiffs have made no showing that they seek merely "factual information" from Drs. Mitchell and Lesko, such that these doctors fall outside the protections of Rule 45(c)(3)(B)(ii). Cf., Arkwright Mut. Ins. Co. v. National Union Fire Ins. Co. of Pennsylvania, 148 F.R.D. 552, 557 (S.D.W. Va. 1993) (discovery of "purely factual information does not comprise the 'intellectual property'" of a witness and is not protected by Rule 45(c)(3)(B)(ii)). For all of these reasons, Drs. Lesko and Mitchell should be afforded the protections of Rule 45(c)(3)(B)(ii).

B. The Court Has Discretion to Quash the Deposition Subpoenas Issued to Drs. Mitchell and Lesko.

Whether a non-party expert, who has not been retained by adversaries in litigation, has a right to resist discovery demands imposed upon him is a question that "addresses itself to the sound discretion of the district court in the first instance." Buchanan v. American Motors Corp., 697 F.2d 151, 152 (6th Cir. 1983). Pursuant to Rule 45(c)(3)(B), the burden is on Langstaff Plaintiffs to show a substantial need for Drs. Mitchell and Lesko's testimony that cannot be otherwise met without undue hardship. In making such a determination, courts continue to rely on the factors set forth in Kaufman v. Edelstein, 539 F.2d 811, 822 (2d Cir. 1976), which is cited to with approval in the Advisory Committee notes to the 1991 Amendment to Rule 45. Kaufman

identified several factors relevant in the consideration of a motion to quash the subpoena of an unretained expert:

Appropriate factors for consideration—some pointing against a dispensation and some for one— would be the degree to which the expert is being called because of his knowledge of facts relevant to the case rather than in order to give opinion testimony; the difference between testifying to a previously formed or expressed opinion and forming a new one; the possibility that, for other reasons, the witness is a unique expert; the extent to which the calling party is able to show the unlikelihood that any comparable witness will willingly testify; the degree to which the witness is able to show that he has been oppressed by having to continually testify; and undoubtedly, many others.

Id.

The first factor to be considered is “the degree to which the expert is being called because of his knowledge of facts relevant to the case rather than in order to give opinion testimony.” Id. Drs. Lesko and Mitchell’s expertise lies in the construction and carrying out of epidemiological studies and their statistical analysis of the resulting data. Neither doctor’s research reflects findings regarding any one individual, and Langstaff Plaintiffs have made no showing as to how the methodology of the Boston University Fever Study relates to Kaitlyn Langstaff’s injuries.

It is unclear whether Drs. Mitchell and Lesko’s testimony is being sought in relation to “a previously formed or expressed opinion [or] a new one.” Id. Langstaff Plaintiffs have not indicated the likely scope of their examination. Without any limits on the scope of the depositions, it is likely that they will attempt to elicit new opinions from Drs. Mitchell and Lesko as to whether Children’s Motrin could have led to the injuries suffered by Kaitlyn Langstaff. This is precisely the sort of forced expert testimony that Rule 45(c)(3)(B)(ii) was designed to guard against.

Similarly, Kaufman's third factor—"the possibility that, for other reasons, the witness is a unique expert," id., supports movants' position. Drs. Lesko and Mitchell's depositions are not necessary. Their research findings have been set forth in published articles that describe their methodology and the results of their studies. See, for example, Exhibit 3. Furthermore, these articles can be placed into evidence without calling Drs. Lesko or Mitchell as a witness pursuant to Fed. R. Evid. 803(18), which creates an exception to the hearsay rule for learned treatises. Langstaff Plaintiffs can easily secure the services of another expert who can review the methodology, contents, and conclusions of Drs. Mitchell and Lesko's published articles.

The fourth factor—"the extent to which the calling party is able to show the unlikelihood that any comparable witness will willingly testify"—places the burden of proving that Drs. Mitchell and Lesko are unique and absolutely necessary witnesses upon Langstaff Plaintiffs. It is highly unlikely that Langstaff Plaintiffs will be able to show that they can only attack the methodology of the study if they are able to depose Drs. Lesko and Mitchell, rather than having their experts testify to any flaws in methodology based on the voluminous study data they have already received from McNeil. See Anker v. G.D. Searle & Co., 126 F.R.D. 515, 521 (M.D.N.C. 1989) (quashing subpoena upon a finding that plaintiffs did not demonstrate that research papers issued by expert were written in such a fashion so as to make it impossible to critically examine and evaluate the reports). Langstaff Plaintiffs have already received the underlying data from the Boston University Fever Study in response to their document production requests propounded upon McNeil. Thus, they have made no showing that Drs. Lesko or Mitchell have information that can only be discovered through deposition.

The fifth Kaufman factor is whether the expert has "been oppressed by having continually to testify." While this has not happened yet, it is important to note that, since the

time McNeil received approval for over-the-counter distribution of pediatric ibuprofen, other drug companies, such as Wyeth Pharmaceuticals, have received similar approval to market pediatric ibuprofen, based on the data that McNeil provided to the FDA, including clinical trials performed by Drs. Mitchell and Lesko. While Drs. Mitchell and Lesko have not yet been subpoenaed to a deposition in connection with the Boston University Fever Study, Dr. Mitchell has recently been subject to a lengthy subpoena duces tecum in connection with a case brought against Wyeth Pharmaceuticals.⁴

The balance of the Kaufman factors show that Langstaff Plaintiffs have not demonstrated “a substantial need for the testimony or materials that cannot be otherwise met without undue hardship.” As such, the subpoenas should be quashed. See Dow Chemical v. Allen, 672 F.2d 1262, 1272 (7th Cir. 1982) (need for information not compelling under the circumstances), Buchanan v. American Motors Corp., 697 F.2d 151 (6th Cir. 1983); (quashing subpoena because too burdensome to have expert explain raw data underlying his research); Biotechnology General Corp. v. Novo Nordisk A/S, 2003 WL 21057238 (D.Del.) (quashing deposition where expert did not possess any unique facts relevant to the case that could not be obtained from retained experts).

C. Langstaff Plaintiffs Have Not Assured that Drs. Mitchell and Lesko Will Be Reasonably Compensated.

Langstaff Plaintiffs have not stated that Drs. Mitchell and Lesko will be compensated at their customary consulting rates for their forced testimony. Because “assurance” of such compensation is required under Rule 45(c)(3)(B)(ii), this Court should, at a minimum, require

⁴ In August of 2003, Dr. Mitchell received a subpoena duces tecum in the case of Madden, et al. v. Wyeth, et al., Civil Action No. 3-03-CV-0167R, United States District Court for the Northern District of Texas. The lawsuit involved claims of injury from pediatric ibuprofen marketed by Wyeth under the name Children’s Advil.